NORTH DAKOTA MEDICAID
TECHNOLOGY/PROCEDURE ASSESSMENT EVALUATION CRITERIA

1. The technology/procedure must have final approval from the appropriate government regulatory bodies.

   - A device, drug or biological product must have Food and Drug Administration approval to market for those specific indications and methods of use that North Dakota Medicaid is assessing.
   - Approval to market refers to permission for commercial distribution. Any other approval that is granted as an interim step in the FDA regulatory process, e.g., as Investigational Device Exemption, is not sufficient.
   - A procedure identified by a valid CPT/HCPCS code.

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.

   - The evidence should consist of well-designed and well-conducted investigations published in peer-reviewed journals. The quality of the body of studies and the consistency of the results are considered in evaluating the evidence.
   - The evidence should demonstrate that the technology/procedure can measure or alter the physiological changes related to a disease, injury, illness or condition. In addition, there should also be evidence or a convincing argument based on established medical facts that such measurement or alteration affects the health outcomes.
   - Opinions and evaluations by national medical associations, consensus panels or other technology/procedure assessment evaluation bodies are evaluated according to the scientific quality of supporting evidence and rationale.

3. The technology/procedure must improve the net health outcome.

   - The technology's/procedure's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.

4. The technology/procedure must be as beneficial as any established alternatives.

   - The technology/procedure should improve the net heatlh outcome as much as or more than established alternatives.

5. The improvement must be attainable outside the investigational settings.

   - When used under the usual conditions of medical practice, the technology/procedure should be reasonably expected to satisfy criteria # 3 and # 4.

NORTH DAKOTA MEDICAID
PROVIDER TECHNOLOGY/PROCEDURE ASSESSMENT DOCUMENTATION

Provider			Address
City	State	Zip Code	Phone Number

1. Description of technology/procedure. (Please include appropriate code attached to technology/procedure.)
2. What are the criteria patients must meet before they can become candidates for use of this technology/procedure?
3. What are the specific indications and methods of use for which this technology/procedure has received (FDA) market approval?
4. How would this technology/procedure benefit patient's health outcome?
5. Indicate relevant peer-reviewed journal references which demonstrate the efficacy and safety of this technology/procedure.
6. What medical associations, consensus panels, and/or other technology/procedure assessment bodies have evaluated the safety and efficacy of this technology/procedure?
7. How would the health outcomes using this technology/procedure compare to the available alternatives?
8. What would be the fixed and variable costs of this technology/procedure?
9. How would the cost of this technology/procedure compare to the alternatives?
10. What would be this technology's/procedure's estimated yearly volume of use?
11. Do you have any financial interest in this technology/procedure?
12. How have other third party payers responded to reimbursement of this technology/procedure?

Please return this assessment to:

Medical Services
ND Department of Human Services
600 E. Boulevard Ave, Dept. 325
Bismarck, ND 58505-0250
Fax: (701) 328-1544